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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/875,945 | 06/08/2001 | Ulf Smith | 45069 | 8408 |

466 7590 12/02/2002

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| EXAMINER |
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CHUNDURU, SURYAPRABHA

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| ART UNIT | PAPER NUMBER |
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1637

DATE MAILED: 12/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/875,945

Applicant(s)

SMITH, ULF

Examiner

Suryaprabha Chunduru

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 7-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The response to restriction requirement (Paper No. 10) filed on October 24, 2002 has been entered and considered.
2. The Preliminary Amendment (Paper No. 6) filed on June 8, 2001 and the Information Disclosure Statement (Paper No. 8) filed on September 10, 2001 have been entered and considered.
3. Applicant's election with traverse of Group I (claims 1-6) and SEQ ID No. 3 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that examining claims in Groups IV and VI along with Claims in Group I would not be a serious burden on the examiner. This is not found persuasive because the claims in Group IV and VI are drawn to an use as a medication (treatment) and a method for diagnosis of IRS-2 related metabolism and are placed in separate class and subclass as compared to claims in Group I. Classification is the prima facie evidence for burden of search. Further (i) the issues are not the same with respect to 35 U.S.C. 112 and 35 U.S.C. 101 statutes, (ii) separate Art Units would examine the two Groups under ordinary circumstances. Thus the restriction requirement is still deemed proper.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- a. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is based on a lack of written description.

The claims are drawn to an isolated and substantially purified nucleotide sequence comprising SEQ ID No. 3. The claims are further drawn to homologues thereof, hybridizable sequence(s) and fragments with at least 70, 80, 90, 95 or 98% homology to the SEQ ID NO.3. Thus, the current claims are broadly drawn to a genus of any fragment(s), which have, from 70 to 98% homology to SEQ ID No.3 or any hybridizable fragment comprising SEQ ID No. 3 or any homologues thereof comprising SEQ ID NO.3. Where homologies greater than 70% are recited, no functional limitations are imposed by the claims. This large genus is represented in the specification by the named SEQ ID No.3. Thus, applicant has expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common elements or attributes of the sequences are disclosed in the sequences with greater than or equal to 70% homology. With regard to the sequences, which have 70% or greater homology, this is insufficient to demonstrate identity of biological function where no structural information regarding where in the nucleic acid sequence the biological function resides. Further no information is given regarding a methodology to determine such common elements or attributes. Further, there is no description of hybridizable fragments. The specification provides insufficient written description to support the genus encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

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in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No. 3 which include modifications by permitted by the "70-98%, hybridizable fragments or homologues thereof" language for which no written description is provided in the specification.

In the instant application, only the nucleic acid sequence of the disclosed SEQ ID No. 3 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that: "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description, which would demonstrate conception or written description of any nucleic acid sequences modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID No. 3 with

retaining correlative function in the claimed product.

Accordingly, the specification does not provide a written description of the invention of claims 1-6.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Birren et al.

(Whitehead Institute/ MIT center for Genome Research, submitted on October 15, 1999).

With reference to the instant claims 1-2 and 5-6, Birren et al. teach an isolated nucleic acid sequence comprising the SEQ ID NO. 3 of the instant claims (see sequence alignment) and has 100% homology with SED ID NO. 3.

With reference to the instant claims 2-4, the nucleic acid sequence of Birren et al. could hybridize under stringent conditions because it has 100% homology to SEQ ID NO.3 of the instant claim 2. The nucleic acid sequence of Birren et al. meets the limitation regarding the homology of at least 70, 80, 90, 95 or 98%, because it has 100% homology with the instant SEQ ID NO. 3. Thus the disclosed nucleic acid sequence of Birren et al. meets the limitations in the instant claims.

Conclusion

No claims are allowable.


Any inquiry concerning this communication or earlier communications from the

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examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
November 27, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER